PATIENT INFORMATION LEAFLET

FEKSINE® 120 mg Film tablet

It is taken orally.

Active* ingredient*: Fexofenadine HCl

Excipients: croscarmellose sodium, microcrystal cellulose, pregelatinized corn starch, colloidal anhydrous silica, povidone K-30, magnessium stearate, lactose monohydrate (obtained from cow's milk), hydroxypropyl methyl cellulose, titanium dioxide, polyethyleneglycol 4000.

Please read these LEAFLET carefully before you start using this medicine because it contains important information for you.

- Keep these leaflet. You can need to read again.
- If you have other questions, please talk your doctor or pharmacist.
- This drug has been prescribed for you personally, please do not give it to others.
- If you go to the doctor or hospital during the use of this medicine, tell your doctor that you are taking it.
- Follow these leaflet exactly. Do not use **high or low doses** other than the recommended dose

In these leaflet :

Headlines are included.

1. What is FEKSINE® and what is it used for?

The active ingredient of FEKSINE® is fexofenadine hydrochloride. 1 film tablet contains 120 mg of fexofenadine hydrochloride. The tablets are white, oblong shaped, film coated.

FEKSINE® is available in cardboard box packages containing blisters of 10 and 20 film tablets.

FEKSINE® is in the group of antihistamine drugs. Antihistamine drugs improve symptoms such as sneezing, itchy runny nose, redness and watering of the eyes, which occur with the disease called hay fever (seasonal allergic rhinitis).

Your doctor may have prescribed FEKSINE® to you or your child over 12 years of age for the relief of the following symptoms due to a disease called chronic idiopathic urticaria:

- Runny nose
- Itching of the nose, palate and throat
- Redness and watering of the eyes

2. Precautions before using FEKSINE®

DO NOT use FEKSINE® in the following cases.

If you are allergic to fexofenadine hydrochloride, which is the active ingredient in FEKSINE® or to any of the other ingredients of the drug

USE FEKSINE® CAREFULLY in the following situations.

If;

- If you have liver or kidney problems,
- If you have had heart disease or have problems with the heart (medicines such as FEKSINE® can cause the heartbeat to accelerate or beat irregularly),
- If you are of advanced age,
- Tell your doctor if you are pregnant, might become pregnant or are breastfeeding.

If these warnings apply to you, even at any time in the past, please consult your doctor.

Pregnancy

Consult your doctor or pharmacist before using this medication.

If your doctor thinks that the benefit of FEKSINE® outweighs the possible harm to your baby, he or she may recommend you to use the drug. Do not use FEKSINE® without consulting your doctor.

If you realize that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breast-feeding

Consult your doctor or pharmacist before using this medication.

The use of FEKSINE® during breastfeeding is not recommended. If you need to be treated with Fexofenadine while breastfeeding, you should stop breastfeeding to protect the baby from small amounts of fexofenadine hydrochloride that is excreted in breast milk.

Vehicle and machine use

It has no known effects on the ability to drive and use machines**.**

Concomitant use with other drugs

- Antacids containing aluminum and magnesium hydroxide (It is recommended to leave a 2-hour period between the administration of FEKSINE® and this type of antacid drugs).

If you are currently using or have recently used any prescription or non-prescription drugs, please inform your doctor or pharmacist about them.

3. How to use FEKSINE®?

Instructions for proper use and frequency of dosage / administration:

The recommended dose of fexofenadine hydrochloride for adults and children aged 12 years and over is 120 mg once daily. (1 per day, FEKSINE® 120 mg Film Tablet)

Method of Administration:

It is taken orally. Swallow the tablets in the amount recommended by your doctor with a glass of water. Take the tablets before meals.

If you are using antacid drugs containing aluminum or magnesium for your indigestion complaints, leave a time interval of 2 hours between taking these drugs and swallowing FEKSINE®.

Different age groups:

Use in children:

FEKSINE® is not used in children younger than 12 years of age, as its safety and efficacy have not been proven yet.

Elderly use:

Use FEKSINE® with caution in patients, as there are limited studies involving elderly patients.

Special use cases:

Kidney / Liver failure:

FEKINE® should be used with caution in the elderly, patients with renal or hepatic impairment. In addition, its use is not recommended in patients with severe renal impairment.

If you have the impression that the effect of FEKSINE® is too strong or weak, talk to your doctor or pharmacist.

If you have used more FEKSINE® than you should:

If you have used more than you should use from FEKSINE®, talk to a doctor or pharmacist.

If you forget to use FEKSINE®:

Do not take double doses to compensate for forgotten doses.

Effects that may occur when treatment with FEKSINE® is discontinued:

If you stop FEKSINE® treatment without your doctor's approval; Your complaints such as redness and itching on the skin may start again.

4. What are the possible side effects?

Like all medicines, there may be side effects in people who are sensitive to the substances in the content of FEKSINE®.

Side effects are classified as:

Very common	: It can be seen in at least one of 10 patients.
Common	: Less than one in 10 patients, but more than one in 100 patients.
Not common	: Less than one in 100 patients, but more than one in 1,000 patients.
Rarely	:(It can be seen less than one in 1000 patients but more than one in 10000 patients)
Very rare	: Less than one in 10,000 patients can be seen.
Unknown	: Unable to estimate from the available data.

If any of the following occur, stop using FEKSINE® and IMMEDIATELY inform your doctor or go to the nearest hospital emergency department:

- If you start breathing with difficulty and wheezing,
- If you experience swelling of your face, tongue or throat that may make it difficult to swallow or breathe

These are all very serious side effects. If you have one of these, you may need emergency medical attention or hospitalization.

Very common:

• Headache (3%),

• Drowsiness (1-3%),

• Dizziness (1-3%),

• Nausea (1-3%),

• Muscle pain (3%) (Myalgia)

Common:

• Insomnia,

• Irritability,

• Sleep disturbances or paronychia

Rarely:

• Redness,

• Urticaria,

• Itching and angioedema,

• Chest tightness,

• Shortness of breath (dyspnea),

• Hypersensitivity reactions with symptoms such as burning sensation and systemic anaphylaxis.

Unknown:

• Fast heartbeat,

• Heart palpitations,

• Diarrhea,

• Redness,

• Itching,

• Urticaria

If you experience any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

5. Storage of FEKSINE®

Keep FEKSINE® out of the reach of children and in its packaging.

Store at room temperature below 25°C and keep it in its original packaging.

Use in accordance with expiration dates.

Do not use FEKSINE® after the expiry date stated on the package.

Do not use FEKSINE® if you notice any defects in the product and/or its packaging.

Do not throw away expired or unused medicines! Give it to the collection system determined by the Ministry of Environment and Urbanization.

Marketing Authorization Holder:

Drogsan İlaçları San. ve Tic. A.Ş.

Oğuzlar Mah. 1370. sok. 7/3 06520 Balgat-ANKARA

Manufacturing Site:

Drogsan İlaçları San. ve Tic. A.Ş.

06760 Çubuk - ANKARA

These leaflet was approved on 21/10/2017.